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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,162	08/24/2001	Johannes Laurenz Kellenberger	0380-P02380U	5244
110	7590	10/06/2004	EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,162

Applicant(s)

KELLENBERGER ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-26 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) 21-23 and 29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,4,6-9,11-18,20,24-26,28 and 30-32 is/are allowed.
- 6) ☒ Claim(s) 3 and 5 is/are rejected.
- 7) ☒ Claim(s) 10 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on October 15, 2003), Applicants filed a response and amendment received on April 16, 2004. Said amendment cancelled Claim 1, amended Claims 2, 4-15, 18, and 19, and added new Claims 30-32. Thus, Claims 2-26 and 28-32 are pending in the instant Office action.

Election/Rejoinder

2. As noted in the previous Office action, Applicants' election without traverse of Group I, Claims 1, 2, 4-19, and 28 in Paper No. 8 is acknowledged.

Claim 15 is directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), Claims 20 and 24-26, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 20 and 24-26 are hereby rejoined and fully examined for patentability under 37 C.F.R. § 1.104. In accordance with the Official Gazette notice, *supra*, process Claim 29, which does not depend from or otherwise include all the limitations of the allowable product, is NOT been rejoined.

Product Claim 3 has also been rejoined herein. By virtue of the prosecution, it is clear that Claim 3 is a genus of Claim 30, as now claimed.

Claims 2-26 and 28-32 are pending in the instant application. Claims 21-23, drawn to different products, and Claim 29, drawn to an independent process claim without the limitations of any of the allowed product claims, remain withdrawn from consideration as non-elected inventions. Claims 2-20, 24-26, 28, and 30-32 will be examined herein.

Priority

3. As previously noted, the instant application is granted the benefit of priority for PCT application PCT/GB9902158 filed on July 6, 1999 and the foreign application 9814622.8 filed on July 6, 1998 in the United Kingdom.

Withdrawn - Objections to the Specification

4. Previous objection to the specification for being confusing with respect to the sequence listing and its 66 sequences is withdrawn by virtue of Applicant's amendment to the specification to include only 61 SEQ ID NOs.

5. Previous objection to the specification for missing a Brief Description of the Drawings is withdrawn by virtue of Applicant's amendment inserting such a section.

Maintained - Objections to the Specification

6. Previous objection to the amendment filed June 27, 2003 under 35 U.S.C. § 132 because it introduces new matter into the disclosure is maintained. Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues that the reference need not be referred to by application number in order to be incorporated. The Examiner does not disagree. However, in the instant case, no identifying feature was disclosed (i.e., docket number). The only identifying feature was a vague title and filing date. As opposed to the Court case Applicant cites, this insertion does not rely on an Example. The Examiner maintains that the information originally filed does not supply adequate support for the particular application number that was inserted in the amendment filed June 27, 2003.

Withdrawn - Objections to the Claims

7. Previous objection to Claim 4 for improper subject/verb agreement is withdrawn by virtue of Applicant's amendment.

Maintained - Objections to the Claims

8. Previous objection to Claims 10 and 19 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that because the claims now depend from Claim 30, they are proper. The Examiner disagrees. Not only is this definition of reductive domain (being KR, DH, or ER) taken directly from the specification and is limiting in Claims 9 and 18, but Claim 30 actually defines the domains as such. Thus, in no way can Claims 9 and 18 encompass reductive domains other than KR, DH, and ER, as would be required for Claims 10 and 19 to further limit.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

9. Previous rejection of Claims 1, 2, 4-19, and 28 under 35 U.S.C. § 112, second paragraph, is withdrawn by virtue of Applicant's amendment.
10. Previous rejection of Claims 2, 8, and 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of "said extension module" is withdrawn by virtue of Applicant's amendment to include an extension module in the base claim that is new Claim 30.

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11. Previous rejection of Claim 6 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "some" is withdrawn by virtue of Applicant's amendment to the term --- one---.

12. Previous rejection of Claim 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of "said at least part of a Type I polyketide synthase" is withdrawn by virtue of Applicant's amendment to the language of Claim 12 as well as its dependency.

13. Previous rejection of Claims 1, 2, 4-19, and 28 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's arguments. The arguments clearly set forth that the intended scope for the length of polylinkers is limited by reasonableness in the art. The Examiner finds this argument convincing.

Maintained - Claim Rejections - 35 U.S.C. § 112

14. Previous rejection of Claim 5 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "absent from at least about half of" is maintained. Applicant argues that the amendment to the phrase "at least one of the restriction sties included in the polylinker is absent from other naturally occurring nucleic acid sequences which encode reductive domains of Type I polyketide synthases" is clear. The Examiner disagrees. As previously noted,

"Polyketide synthase gene clusters are being discovered constantly. Half of their number at the time of filing of the instant application could be double the number of half their number today. Moreover, newly identified PKS gene cluster could contain previously unknown restriction sites to PKS gene clusters. And additionally, even new restriction enzyme sites are being discovered which lends another level of ambiguity to the phrase. Thus, the metes and bounds of the claim remain unclear."

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15. Previous rejection of Claim 5 under 35 U.S.C. § 112, first paragraph, new matter, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the amendment deleting "from at least half" obviates the rejection; the Examiner disagrees. As previously noted, the cited support for the amendment describes "how restriction sites should be 'absent from the remainder of the nucleic acid into which it is incorporated' or how 'at least half of the sites' should be absent from the remainder for the nucleic acid into which it is incorporated. The amendment to Claim 5 applies this limitation such that the restriction sites are absent from other naturally occurring PKSs with reductive domains, regardless of their incorporation with polylinkers or not. In other words, this portion of the specification makes it clear that the restriction sites must be absent 'from the remainder of the nucleic acid' and not necessarily from all known PKSs in the art." For these reasons, the amendment to Claim 5 is still considered new matter.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claim 3 is rejected under 35 U.S.C. § 102(b) as being anticipated by Eikmanns *et al.* (A family of *Corynebacterium glutamicum*/*Escherichia coli* shuttle vectors for cloning, controlled gene expression, and promoter probing. Gene (1991) 102(1): 93-98). The instant claim is drawn to a nucleic acid encoding a part of a type I PKS wherein a polylinker connects a part of

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an AT domain and a part of an ACP domain; since no limitations on "part" is found, this reads on as little as a single nucleotide.

Eikmanns *et al.* teach pEK0 and pEC5 that carry multiple restriction sites; such plasmids read on the instant claim.

Summary of Pending Issues

17. The following is a summary of the issues pending in the instant application:

- a) The amendment filed June 27, 2003 stand objected to under 35 U.S.C. § 132 because it introduces new matter into the disclosure.
- b) Claims 10 and 19 stand objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.
- c) Claim 5 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "absent from other naturally occurring nucleic acid sequences which encode reductive domains of Type I polyketide synthases"
- d) Claim 5 stands rejected under 35 U.S.C. § 112, first paragraph, new matter.
- e) Claim 3 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Eikmanns *et al.*

Conclusion

18. Claims 2, 4, 6-9, 11-18, 20, 24-26, 28, and 30-32 are allowed in the Office action; claims 3, 5, 10, and 19 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

The instant Office action is non-final due to the new rejection required by virtue of the rejoinder of Claim 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

October 1, 2004